

PATENT
Attorney Docket No.: 10139 - 14705 (00864-06PUS1)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)
Kropf et al.)
Serial No.: 10/597,847) Group Art Unit: 3738
Filed: August 9, 2006) Examiner: Megan Yarnall Wolf
For: PROSTHESIS FOR REPLACING)
THE SURFACE IN THE AREA OF)
THE BALL-AND-SOCKET)
JOINTS)
 **Board of Patent Appeals and
 Interferences**

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed December 18, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 18 - 36 and 40 - 42 in the Final Office Action dated September 29, 2008. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Synthes (U.S.A.) which is a wholly owned subsidiary of Synthes, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1 - 17 and 37 - 39 have been canceled. Claims 18 - 36 and 40 - 42 stand rejected in the Final Office Action. The final rejection of claims 18 - 36 and 40 - 42 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

As recited in independent claim 18, the present invention is directed to a prosthesis 1 for replacing a surface of a ball of a ball-and-socket joint. (*See Specification, ¶ [0012], [0025]; Fig. 2*). The prosthesis 1 comprises a spherical shell section 2 having an outer surface 3 that is configured to lie in an articular fossa and for attachment to a surface, the shell section 2 having a cavity for receiving a bone end. (*Id. at ¶ [0026] - [0028], Figs. 1 - 2, 4 - 5*). The prosthesis 1 further comprises a crown 5 that partitions the cavity of the shell section 2 into first and second

cavities 13, 14 adapted to receive the bone end, wherein the shell section 2 comprises less than a hemisphere and a free edge of the crown 5 lies in the same plane as a free edge of the shell section 2. (*Id.* at ¶ [0028] - [0029]; Figs. 1 - 2, 4 - 5).

As recited in independent claim 36, the present invention is also directed to a prosthesis 1 for replacing a surface in a ball of a ball-and-socket joint. (*Id.* at ¶ [0012], [0025]; Fig. 2). The prosthesis 1 comprises a spherical shell section 2 having an outer surface 3 configured to lie in an articular fossa and for attachment to a surface, the shell section 2 having a cavity for receiving a bone end. (*Id.* at ¶ [0026] - [0028], Figs. 1 - 2, 4 - 5). The prosthesis 1 further comprises a crown 5 that partitions the cavity of the shell section 2 into a first cavity 13 and a second cavity 14, the first and second cavities 13, 14 being adapted to receive portions of the bone end. (*Id.* at ¶ [0028] - [0029]; Figs. 1 - 2, 4 - 5). Claim 36 also recites that the shell section 2 comprises less than a hemisphere and a free edge of the crown 5 does not intersect a plane in which a free edge of the shell section lies. (*Id.* at ¶ [0029]; Figs. 2, 4).

As recited in independent claim 41, the present invention is also directed to a procedure for implantation of a prosthesis 1 in a bone comprising a step of preparing the bone and forming a groove in the bone. (*Id.* at ¶ [0012], [0031]; Fig. 1). Claim 41 also recites providing a prosthesis 1 for replacing a surface in an area of a ball of a ball-and-socket joint, the prosthesis 1 including a spherical shell section 2 and a crown 5, the shell section 2 having an outer surface 3 configured to lie in an articular fossa and for attachment to a surface, the shell section 2 having a cavity for receiving a bone end, the crown 5 partitioning the cavity of the shell section 2 into a

first cavity 13 and a second cavity 14, wherein the shell section 2 comprises less than a hemisphere and a free edge of the crown 5 lies in the same plane as a free edge of the shell section. (*Id.* at ¶ [0026] - [0029], [0031]; Figs. 1 - 2, 4 - 5). Claim 41 also recites a step of inserting the prosthesis 1 onto the bone such that the crown 5 is received in the groove formed in the bone. (*Id.*).

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 18 - 42 are unpatentable under 35 U.S.C. § 103(a) as anticipated by Sutter et al. (U.S. Pat. No. 4,332,036) ("Sutter") in view of Lakin (U.S. Published Appln. No. 2003/0163202) ("Lakin").

7. Argument

I. The Rejection of Claims 18 - 36 and 40 - 42 Under 35 U.S.C. § 103(a) as Unpatentable over Sutter in view of Lakin Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 18 - 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter in view of Lakin. (See 9/2908 Office Action, pp. 2 - 9).

B. Sutter and Lakin Do Not Teach or Suggest A Crown That Partitions The Cavity of The Shell Into First And Second Cavities Adapted To Receive The Bone End, Wherein The Shell Section Comprises Less Than A Hemisphere And A Free Edge Of The Crown Lies In The Same Plane As A Free Edge Of The Shell Section, as Recited in Claim 18.

Claim 18 recites a prosthesis for replacing a surface of a ball of a ball-and-socket joint comprising “a spherical shell section having an outer surface that is configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end; and a crown that partitions the cavity of the shell section into first and second cavities adapted to receive the bone end; wherein the shell section comprises less than a hemisphere and *a free edge of the crown lies in the same plane as a free edge of the shell section.*”

It is respectfully submitted that Sutter fails to teach or suggest a prosthesis wherein “a free edge of the crown lies in the same place as a free edge of the shell section,” as recited in claim 18. In support of the rejection, the Examiner has referenced the sleeve *s* of Sutter, citing specifically that Sutter teaches that “the shell *s* is desirably less than 40% of the length of the crown.” (*See* 9/29/08 Office Action, p. 3). However, it is respectfully submitted that Sutter only teaches that “the distance *s* [by which the sleeve 7 extends out of the cap 3] is at most 50%, and preferably at most 40% of length L.” (*See* Sutter, col. 4, l. 20 - 27; Fig. 3). Specifically, although Sutter teaches that the length of the portion *s* may vary, there is no teaching or suggestion in Sutter that the portion *s* is removed altogether to provide a coplanar arrangement. Rather, since Sutter explicitly teaches that the sleeve 7 *must* extend out of the cap 3 by the minimum distance *s*, it is respectfully submitted that Sutter teaches away from such an embodiment. (*Id.*) Furthermore, it is noted that the only limitation Sutter places on the length of the sleeve *s* is that the value of *s* must be chosen such that the sleeve 7 does not extend up the

main vein strand 11g of the bone. (See Sutter, col. 6, ll. 29 - 34; Fig. 6). Nothing in Sutter shows or suggests that the portion *s* can be eliminated entirely. In fact nothing suggests that it could be less than 30% of the length *L* or 35%, etc. Accordingly, it is submitted that Sutter only teaches that the distance by which the sleeve 7 protrudes distally out of the cap 3 may be varied, not that the sleeve 7 does not protrude distally at all. Additionally, modifying the device of Sutter so that the sleeve 7 does not project out of the cap 3 at all would be detrimental to the device of Sutter since Sutter explicitly teaches the desirability of such an extension. Specifically, Sutter recites that “[s]ince sleeve 7 protrudes deeper in the femur by the amount *s* than the latter is embraced by the cap, *the risk that the femur will be sheared off at the edge 3b of cap 3 with large forces acting transverse to the rotational symmetry axis 5 is very small.*” (See Sutter, col. 6, ll. 25 - 29). It is therefore submitted that employment of a sleeve 7 that does not extend distally out of the cap 3 would be contrary to the teachings of Sutter and the modification proposed by the Examiner is therefore not allowable.

Lakin does not cure the aforementioned deficiency of Sutter. Specifically, Lakin fails to disclose or suggest that connection member 20 lies in the same plane as the shell section. (See Lakin, p. 2, ¶ [0032]-[0033]; Fig. 1).

It is therefore respectfully submitted that Sutter and Lakin, taken alone or in combination, fail to teach or suggest a prosthesis for replacing a surface of a ball of a ball-and-socket joint comprising a “shell section having a cavity for receiving a bone end; and a crown that partitions the cavity of the shell section into *first and second cavities adapted to receive the*

bone end; wherein the shell section comprises less than a hemisphere and a free edge of the crown lies in the same plane as a free edge of the shell section,” as recited in claim 18 and that claim 18 is therefore in condition for allowance. Since claims 19-35 and 42 depend from and therefore include all of the limitations of claim 18, it is respectfully submitted that these claims are also allowable.

Claim 41 also recites limitations substantially similar to those of claim 18, including a procedure for implantation of a prosthesis in a bone comprising the steps of “providing a prosthesis for replacing a surface in an area of a ball of a ball-and-socket joint, the prosthesis including a spherical shell section and a crown, the shell section having an outer surface configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end, the crown partitioning the cavity of the shell section into a first cavity and a second cavity, *wherein the shell section comprises less than a hemisphere and a free edge of the crown lies in the same plane as a free edge of the shell section;* and inserting the prosthesis onto the bone such that the crown is received in the groove formed in the bone.” It is therefore respectfully submitted that claim 41 is allowable over Sutter and Lakin for at least the same reasons previously mentioned with respect to claim 18.

Claim 36 recites a prosthesis for replacing a surface in a ball of a ball-and-socket joint comprising “a spherical shell section having an outer surface configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end; and a crown that partitions the cavity of the shell section into a first cavity and a second cavity,

the first and the second cavities being adapted to receive portions of the bone end; *wherein the shell section comprises less than a hemisphere and a free edge of the crown does not intersect a plane in which a free edge of the shell section lies.*” As noted above with regard to claim 18, Sutter only teaches a sleeve 7 that is adapted to protrude distally out of the cap 3 by a distance s. (See Sutter, col. 4, l. 20 - 27; Fig. 3). Thus, it is submitted that Sutter fails to teach or suggest a sleeve 7 wherein “a free edge [thereof] does not intersect a plane in which a free edge of the shell lies,” as recited in claim 36. It is further submitted that Lakin fails to overcome this deficiency. Specifically, Lakin does not teach a “shell section having a cavity for receiving a bone end” wherein “the shell section comprises less than a hemisphere and a free edge of the crown does not intersect a plane in which a free edge of the shell section lies,” as recited in claim 36 at all.

It is therefore respectfully submitted that neither Sutter nor Lakin, taken alone or in combination, teach or suggest “a spherical shell section having an outer surface configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end” wherein “the shell section comprises less than a hemisphere and a free edge of the crown does not intersect a plane in which a free edge of the shell section lies,” as recited in claim 36 and claim 36 is therefore allowable over Sutter and Lakin. Since claim 40 depends from and therefore includes all of the limitations of claim 36, it is respectfully submitted that this claim is also allowable.

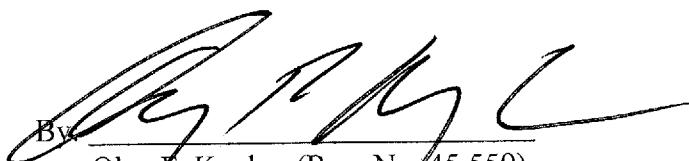
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8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a) and indicate that claims 18 - 36 and 40 - 42 are allowable.

Respectfully submitted,

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CLAIMS APPENDIX

1 - 17. (Canceled)

18. (Previously Presented) A prosthesis for replacing a surface of a ball of a ball-and-socket joint comprising:

a spherical shell section having an outer surface that is configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end; and

a crown that partitions the cavity of the shell section into first and second cavities adapted to receive the bone end;

wherein the shell section comprises less than a hemisphere and a free edge of the crown lies in the same plane as a free edge of the shell section.

19. (Previously Presented) The prosthesis of claim 18, wherein the spherical shell section has a height h that is about 65% to 90% of a radius of the ball.

20. (Previously Presented) The prosthesis of claim 19, wherein the spherical shell section has a height h that is about 70% to 85% of the radius of the ball.
21. (Previously Presented) The prosthesis of claim 19, wherein the spherical shell section has a height h that is about 80% of the radius of the ball.
22. (Previously Presented) The prosthesis of claim 18, wherein the first cavity has a circular shape and the second cavity has an annular shape.
23. (Previously Presented) The prosthesis of claim 18, wherein an innermost end of the crown is integrally connected to an inner surface of the shell section so as to form a single integral structure.
24. (Previously Presented) The prosthesis of claim 18, wherein at least one of an inner surface of the shell section and a surface of the crown is configured for contact with the bone end and is therefore a roughened surface.
25. (Previously Presented) The prosthesis of claim 18, wherein the crown has at least one opening formed therein to provide communication between the first and second cavities.

26. (Previously Presented) The prosthesis of claim 25, wherein the at least one opening comprises at least five openings.
27. (Previously Presented) The prosthesis of claim 18, wherein at least one of an inner surface and an outer surface of the crown has a relief structure formed as a part thereof.
28. (Previously Presented) The prosthesis of claim 27, wherein the relief structure comprises a fluting that is formed by ring beads that extend circumferentially around the crown.
29. (Previously Presented) The prosthesis of claim 18, wherein the inner surface of the shell section includes a relief structure that extends along an edge of the shell section.
30. (Previously Presented) The prosthesis of claim 29, wherein the relief structure comprises fluting formed circumferentially around the inner surface of the shell section.
31. (Previously Presented) The prosthesis of claim 18, wherein the crown and shell section are separate parts and are constructed to be securely coupled to one another.
32. (Previously Presented) The prosthesis of claim 31, wherein the crown and shell section are constructed to be threadingly coupled to one another by means of threads formed on at least

one of an outer surface of the crown and an inner surface of the shell section.

33. (Previously Presented) The prosthesis of claim 18, wherein the crown has a shape selected from the group consisting of a circle and a polygon.

34. (Previously Presented) The prosthesis of claim 18, wherein the crown is arrayed in a coaxial manner.

35. (Previously Presented) The prosthesis of claim 18, wherein the crown and shell section are individual parts and are connected to one another by a mechanical fit selected from the group consisting of screw threading, a bayonet joint and a clamping device.

36. (Previously Presented) A prosthesis for replacing a surface in a ball of a ball-and-socket joint comprising:

a spherical shell section having an outer surface configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end; and

a crown that partitions the cavity of the shell section into a first cavity and a second cavity, the first and the second cavities being adapted to receive portions of the

bone end;

wherein the shell section comprises less than a hemisphere and a free edge of the crown does not intersect a plane in which a free edge of the shell section lies.

37 - 39. (Canceled)

40. (Previously Presented) The prosthesis of claim 36, wherein the free edge of the crown is up to about 5 mm from the plane containing the free edge of the shell section.

41. (Previously Presented) A procedure for implantation of a prosthesis in a bone comprising the steps of:

preparing the bone and forming a groove in the bone;

providing a prosthesis for replacing a surface in an area of a ball of a ball-and-socket joint, the prosthesis including a spherical shell section and a crown, the shell section having an outer surface configured to lie in an articular fossa and for attachment to a surface, the shell section having a cavity for receiving a bone end, the crown partitioning the cavity of the shell section into a first cavity and a second cavity, wherein the shell section comprises less than a hemisphere and a free edge of the crown lies in the

same plane as a free edge of the shell section; and

inserting the prosthesis onto the bone such that the crown is received in the groove formed in the bone.

42. (Previously Presented) A set of prostheses comprising:

a plurality of prostheses according to claim 18, wherein the shell sections are formed having diameters that differ from one another and wherein a ratio of a height (h) of the shell section to a respective ball diameter is equal for each prosthesis and wherein a diameter of each crown amounts to the same percentage of a diameter of the spherical shell section for each prosthesis.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.